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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/758,593	01/10/2001	Michael G. Walker	PC-0025 CIP	9627

27904 7590 12/31/2002

INCYTE GENOMICS, INC.  
3160 PORTER DRIVE  
PALO ALTO, CA 94304

EXAMINER

LI, RUIXIANG

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 12/31/2002

18

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/758,593

Applicant(s)

WALKER, MICHAEL G.

Examiner

Ruixiang Li

Art Unit

1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 19 November 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-9 is/are allowed.
- 6) ☒ Claim(s) 10-12 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### **I. Status of Application, Amendments, and/or Claims**

The amendment filed in Paper No. 17 on November 19, 2002 has been entered in full. Claims 13-21 have been canceled. Claims 1-12 are pending.

The finality of the office action in Paper No. 16 mailed on October 10, 2002 has been withdrawn upon applicant's request to rejoin methods of claims 7-12 in accordance with MPEP § 821.04 and *in re Ochiai*.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

### **II. Withdrawn Rejections**

The rejection of Claims 1, 2, 4, and 5 under 35 U.S.C. 102 (a) and the rejection of Claims 3 and 6 under 35 U.S.C. 103 (a), as set forth in the previous Office Action (Paper No. 9, May 1, 2002), have been withdrawn in view of a declaration under 37 CFR 1.131 signed by the sole inventor, Michael G. walker, demonstrating the instantly claimed invention was conceived prior to the publication date of the reference by Pallavicini et al, December 21, 2000.

### **III. Claim Rejections—35 USC § 112, 1<sup>st</sup> paragraph**

(i) The following is a quotation of the first paragraph of 35 U.S.C. 112:

Art Unit: 1646

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

(ii) Claim 10 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of using the claimed cDNA for diagnosis of clear cell sarcoma, wherein the cDNA is highly expressed in a sample when compared with normal musculoskeletal tissues, does not reasonably provide enablement for a method of using a cDNA for diagnosis of clear cell sarcoma, wherein the cDNA expression is relatively lower in a sample when compared with that in normal musculoskeletal tissue. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with the claim.

The factors considered when determining whether a disclosure satisfies enablement requirement include: (i) the quantity of experimentation necessary; (ii) the amount of direction or guidance presented; (iii) the existence of working examples; (iv) the nature of the invention; (v) the state of the prior art; (vi) the relative skill of those in the art; (vii) the predictability or unpredictability of the art; and (viii) the breadth of the claims. *Ex Parte Forman*, 230 USPQ 546 (Bd Pat. App. & Int. 1986); *In re Wands*, 858 F. 2d 731, 8 USPQ 2d 1400 (Fed. Cir. 1988).

Claim 10 is drawn to a method for using a cDNA to detect expression of a nucleic acid in a sample, wherein the cDNA is differentially expressed when compared with a standard and diagnostic of clear cell sarcoma. The Examiner notes that the term "differentially expressed" encompasses both a higher degree of

Art Unit: 1646

expression or a lower degree of expression when compared with the expression of the cDNA in normal musculoskeletal tissues. From the instant disclosure, it is apparent that only the higher degree of expression of the cDNA is diagnostic clear cell sarcoma (2<sup>nd</sup> paragraph of page 10; Figure 3B). There is no disclosure on the method of diagnosis for clear cell sarcoma, wherein the cDNA is expressed in a lower degree when compared with normal musculoskeletal tissues.

In addition, it is unclear what “a standard” encompasses here in the instant claim. Without the unambiguously defined “standard”, one skilled in the art would not be able to perform the claimed method. Therefore, it would require undue experimentation for one skilled in the art to use the claimed invention commensurate in scope with the claim.

#### **IV. Claim Rejections—35 USC § 112, 2<sup>nd</sup> paragraph**

(i) The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

(ii) Claims 10-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 10 is indefinite because it recites the term “a standard”. It is unclear what the metes and bounds the term are.

Claim 11 is indefinite because the preamble of the claim is ambiguous and it fails to point out clearly the nature of the claimed invention. It appears that the method is

Art Unit: 1646

intended to be drawn to a method of using the cDNA to screen a plurality of molecules for those that bind to the cDNA, and amendment accordingly would overcome this rejection.

Claim 11 is indefinite also because the steps set forth in the methods do not necessarily achieve the goal of identifying cDNA-binding compounds. It is unclear how a single compound that binds to the cDNA can be identified by the claimed two steps, i.e., combining the cDNA with a plurality of molecules and detecting their binding.

Claim 12 is indefinite because it recites "peptide nucleic acids", "repressors", and "regulatory molecules". It is unclear what the metes and bounds the terms are.

## **V. Conclusion**

Claims 1-9 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruixiang Li whose telephone number is (703) 306-0282. The examiner can normally be reached on Monday-Friday, 8:30 am-5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564. The fax phone number for this Group is (703) 305-3014 or (703) 308-4242.

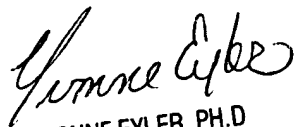
Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [yvonne.eyler@uspto.gov].

Art Unit: 1646

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Ruixiang Li  
Examiner  
December 23, 2002

  
YVONNE EYLER, PH.D  
SUPERVISORY PATENT EXAMINER  
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